GP-1801/14

PATENT
Docket No. 220002016004
Client Ref. UC80-065-4

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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10/14/97
Date

Tiffany E. Montgomery

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Walter L. MILLER et al.

Serial No.: 08/487,312

Filing Date: 7 June 1995

For: BOVINE GROWTH HORMONE

Examiner: C. Saoud

Group Art Unit: 1801

TRANSMITTAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Enclosed please find the following:

1. Reply Brief Under 37 CFR 1.193(b) and Request for Oral Hearing
2. Two (2) exhibits
3. Request for Oral Hearing
4. Check in the amount of $270.00

The Assistant Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17, and 1.21 that may be required by this transmittal, or to credit any

overpayment, to **Deposit Account No. 03-1952**.

Dated: October 13, 1997

Respectfully submitted,

By: Kate H. Murashige

Kate H. Murashige
Registration No. 29,959

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PATENT
Docket No. 220002016004

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10/21/97
Date

Tiffany E. Montgomery

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the application of:

MILLER et al.

Serial No.: 08/487,312

Filing Date: 7 June 1995

For: BOVINE GROWTH HORMONE

Examiner: C. Sauod

Group Art Unit: 1801

REQUEST FOR ORAL HEARING PURSUANT TO 37 C.F.R. § 1.194(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

An Oral Hearing is requested in this Appeal.

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This request is made within two months of the Examiner's Answer which was dated September 4, 1997 as required by 37 C.F.R. § 1.194(b).

The Oral Hearing Fee is $270.00.

☒ The Fee for the Oral Hearing is enclosed.

☐ Please charge the fee for the Oral Hearing to **Deposit Account No. 03-1952.**

The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this request, or to credit any overpayment to **Deposit Account No. 03-1952**. A duplicate copy of this request is enclosed for that purpose.

Dated: October 14, 1997

Respectfully submitted,

By: Kate H. Murashige

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PATENT
Docket No. 220002016004
Client Ref. UC 80-065-4

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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10/14/97
Date

Tiffany E. Montgomery

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Walter L. MILLER et al.

Serial No.: 08/487,312

Filing Date: 7 June 1995

For: BOVINE GROWTH HORMONE

Examiner: C. Saoud

Group Art Unit: 1801

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REPLY BRIEF UNDER 37 CFR 1.193(b)
AND REQUEST FOR ORAL HEARING

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

First, appellants wish to call the attention of the Board to the existence of Interference No. 103,925 which was declared in a Notice mailed 16 July 1997. This Interference involves U.S. Serial No. 07/480,745; the present case is a divisional of that application. The Interference is directed to recombinant materials which are related to bovine growth hormone.

Second, appellants wish to address what appears to be the only new argument raised in the Examiner's Answer. This is the statement that "Arguments regarding FDA regulations do not appear to bear on this issue" -- that is, the issue of whether the bovine growth hormone of Daniels *et al.* anticipates or makes obvious the recombinant bovine growth hormone of the instant claims. On the contrary, such regulations do bear on this issue, because such regulations

and the facts on which they are based, in effect, determine whether or not the composition claimed will or will not be useful. It is not the FDA regulations *per se* that are relevant, but rather the reason that they are made. They are made because the product of the prior art cannot be guaranteed to be safe[1] and it is not conscionable to use a product whose safety cannot be guaranteed in the face of the availability of a product that is equally effective for the same purpose whose safety is beyond question. It is undisputed that human growth hormone extracted from pituitaries became effectively useless as such preparations had a probability, even a vanishingly small one, of carrying the infectious agent for Creutzfeldt-Jakob's Disease, when the recombinant form of human growth hormone could be substituted. Similarly, here, the prior art composition of Daniels is effectively useless in view of the availability of the recombinant bovine growth hormone claimed.

The characteristics of a composition of matter are not confined to its physical and chemical properties. Compositions of matter have additional characteristics which relate to the guarantees associated with them. To fail to recognize such characteristics is to deny the importance of an important element of the intellectual property system itself -- namely trademarks. The maker of a counterfeit Gucci wallet may, in fact, create a wallet that is indistinguishable from that that legitimately bears the trademark, but no one would deny the value added by the legitimately added mark, or argue that the products are equivalent. Why? Because it is clear that the reputation of Gucci stands behind the quality of the legitimate product and this does not attach to the counterfeit.

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[1] Reference is again made to the article in *Science* submitted along with applicants' response to the first Office action: *Science* (1985) 228:1176-1177. Column 2, paragraph 2 of that article states that "no virus was present after the pituitary extracts had been purified." This cannot be determinative of safety. It is completely uncertain whether the causative agent for mad cow disease is present in the extracts. Since the Examiner's Answer was written, the Nobel Prize has been awarded to Stanley Prusiner for his work on prions as being the causative agent of this disease. A copy of a report of this award is attached as Exhibit A. If the causative agent is a *prion*, the absence of any *virus* is irrelevant. There is no concern regarding this matter in connection with the administration of recombinant bovine growth hormone. See the enclosed article by Juskevich, J.C. *et al. Science* (1990) 249:875-849 which reports FDA's evaluation of the safety of *recombinant* bovine growth hormone. (Exhibit B)

Similarly, here, the fact of the recombinant production of bovine growth hormone confers upon it a value characteristic that cannot be conferred on the product of Daniels. However low the probability might be that Daniels' bovine growth hormone contained the causative agent for mad cow disease, the guarantee of the recombinant production method for assuring this absence cannot be associated with Daniels' product.[2]

Appellants do not believe that this issue as it applies to patent law has been adjudicated. The cases cited in the Examiner's Answer do not address it. For example, in *Ex parte Gray*, 10 USPQ2d 1922 (BPAI 1989), although the recombinantly produced nerve growth factor was said to be free of other human proteins, there was no argument that this or any other feature made a critical difference. Indeed, the Board, in *Gray*, enunciated the very same test that applicants regard as dispositive: "The dispositive issue before us is whether the claimed factor exhibits any unexpected properties compared with that described by the cited publication items."[3] In addition, in *Gray*, the prior art actually provided a method to make the claimed nerve growth factor; here, the prior art does not -- indeed, the divisional application herein relating to the recombinant method for production has been allowed. Finally, as the Board stated in *Gray*, an acknowledged difference of a single methyl group in a prior art form of the factor from that claimed was not sufficient, in the absence of evidence to the contrary, to impart patentability to the compound. This is far from the case here where the process of preparation confers a valuable property on the product.

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[2] There is no question that Daniels' product and the product of the invention are not identical, even if a host cell were used that effected posttranslational modifications equivalent to those existing in Daniels' product. This is because products purified to apparent homogeneity will contain small amounts of impurities that are undetectable by whatever methods are currently available. These impurities will be different for Daniels' products isolated from pituitaries as compared to those in recombinantly produced bovine growth hormone produced in other cells.

[3] The word "unexpected" was appropriate in *Gray*, but not here. It is recognized that recombinantly produced bovine growth hormone is not expected to be contaminated with the causative agent for mad cow disease. However, it is only through appellants' invention that a composition thus free is made available.

In *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 9 USPQ2d 1833 (Fed. Cir. 1989) the issue was not one of patentability, but rather whether recombinantly produced erythropoietin fell within the scope of a claim directed to erythropoietin having specified properties. That is an entirely different issue from that presented here. Finally, in *Scripps Clinic & Research Foundation v. Genentech Inc.*, 3 USPQ2d 1481 (ND CA 1987) the issue was again whether a recombinantly produced protein infringed a claim which merely specified purity characteristics of Factor 8. Again, the issue is different. Here the issue is whether the process limitation imposes a characteristic on the product that is not met by the prior art which prior art provides no means to obtain that characteristic.

Finally, the Examiner's Answer misapplies appellants' statement that they do not rely on the patentability of the recombinant process for patentability of the claimed bovine growth hormone. What appellants meant was exactly that and only that. It is, of course, germane that absent appellants' invention a recombinant method to make bovine growth hormone was unavailable in the art. *In re Wakefield* is thus not distinguishable, based on appellants' statement, from the case here.

An oral hearing on this issue is requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, appellants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this

document to **Deposit Account No. 03-1952**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 10, 1997

Respectfully submitted,

By: _____

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